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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,292	03/21/2001	De-Chao Yu	348022001500	4803
24353	7590	07/28/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,292

Applicant(s)

YU ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 54, 56, 58-61, 63-70, 78, 79, 82, 83 and 104-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 54, 56, 58-61, 63-70, 78, 79, 82, 83, 104 and 105 is/are rejected.
- 7) ☒ Claim(s) 106 and 107 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of amendments filed 2/20/2004 and 5/11/2004. As a result of these submissions, claims 1-5, 54, 56, 58-61, 63-70, 78-79, 82-83 and 104-107 are pending in the instant action. Applicants' response and the amendment to the pending claims have overcome the outstanding grounds of rejection.

This action is FINAL. The newly presented grounds of rejection based on obviousness-type double-patenting will not preclude the finality of this Office Action. Indeed, these grounds of rejection involves conflicting claims in a copending application newly discovered by the Examiner, which has inventor(s) in common with the present application, and Applicants did not call the attention of the Office to this application. Applicants will not be permitted to extend the prosecution of the present application by reason of their inaction with regard to notice to the Office of conflicting claims in a copending application, the discovery of which necessitated the new grounds of rejection at this advanced state of prosecution. Indeed, with appropriate notice, these grounds of rejection clearly could have been incorporated in a prior Office Action. This situation is clearly analogous to the policy of making an action final where Applicant's material amendments to the claims necessitated a new ground of rejection, since in both instances it is the applicant who caused the rejection to be applied after the case had received an action on the merits. See M.P.E.P. § 706.07(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 54, 56, 58-61, 63-70, 78-79, 82-83 and 104-105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5-6, 9-12, 15, 21, 29, 40-41 of U.S. Patent No. 6,692,736. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. **This is a new rejection.**

The claims of the '736 patent are directed to a replication-competent adenovirus vector comprising a first and second gene operatively linked to a single transcriptional regulatory element (TRE) wherein the TRE is target cell specific with regard to regulating transcriptional activity. At least one of the operatively linked genes can be a gene essential for adenoviral replication, either a late or early adenoviral gene. The early essential gene can be E1A or E1B. The adenoviral vector can further comprise a gene encoding the adenovirus death protein (ADP). The adenoviral vector can comprise the E3 region.

The claims of the instant application are directed to uroplakin II transcriptional regulatory elements comprising specific sequences obtained from either the human uroplakin II promoter (SEQ ID NO: 1) or the murine uroplakin II promoter (SEQ ID NO: 2). These uroplakin II TRE elements can be comprised within an adenoviral vector comprising an adenoviral gene essential

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for replication under control of the uroplakin II TRE. The adenoviral vector can comprise the E3 region and/or the adenoviral death protein gene.

The claims of the '736 patent do not specifically recite any particular TRE element. In order to practice the claimed invention of the '736 patent, one of skill in the art would necessarily need to read the specification to learn which TRE elements are contemplated for the claimed invention. In particular, the '736 patent contemplates using human and mouse uroplakin II promoter sequences that would meet each of the limitations of the instant claims (it is noted the instant claims recite specific fragments, but do so with open "comprising" language). It would have been obvious, therefore, for the skilled artisan to utilize the uroplakin II TRE elements taught by the '736 patent in constructing and using the adenoviral vectors of the patent. Such vectors comprising the mouse or human uroplakin TRE elements taught by the patent would necessarily meet and anticipate the instant claim limitations. Therefore, the rejected claims are necessarily obvious over the cited claims from the '736 patent.

Conclusion

No claims are allowed. Claims 106-107 are objected to as being dependent upon rejected claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GERY LEFFERS
PRIMARY EXAMINER

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

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